

REMARKS

Claims 17-19, 27, 45-47 and 49-58 as presented in Applicants' Preliminary Amendment filed April 13, 2009 remain pending herein. Support for these claims can be found throughout the specification and drawings.

The Examiner has objected to the specification as filed to provide proper antecedent basis for the claim limitation "pleated" as it appears in the recitation "second, folded configuration having a multiplicity of pleated folds" (Claims 17-19, 27, 45-47, 49 and 50). The Examiner cites 37 C.F.R. 1.75(d)(1) and MPEP §608.01(o) in connection with this objection.

By way of satisfying the foregoing objection to the specification and in keeping with aforecited MPEP §608.01(o)¹, Applicants have amended the specification to recite "pleated" in the brief description of FIG. 10 that appears on page 6 and in the more extensive description of Fig. 10 that appears on page 19. Applicants attach hereto a copy of the definition for "pleat" in "Websters New World Dictionary of the American Language" (Simon and Schuster, 1984). As indicated by this definition, an ordinary meaning of "pleated" is a material such as cloth which has been given a pleat (double fold) or series of pleats (multiple double folds). The meaning of "pleated" as a material that has been given a series of double folds aptly applies to the folded implant illustrated in Fig. 10 of the drawings.

The term "pleated" was chosen by Applicants in order to better describe the type of fold that is achieved by pulling on the drawstring of the tissue as it is being implanted as illustrated in the sequence of drawings beginning with Fig. 7 and ending with Fig. 10 and to further differentiate the fully implanted structure over twice folded sheet 14 of Fig. 3A of Muhanna which is *not* a pleated structure in the dictionary sense, but a structure resulting from two single folds being placed at right angles to each other. Applicants will have more to say regarding this important difference

¹ MPEP §608.01(o) permits the amendment of a specification to include a new term where the new term has been introduced into a claim by amendment so as to provide clear support or antecedent basis in the specification for the new term.

between their fully implanted device (and the manner by which it is obtained) and the altogether different implant and method of inserting the implant disclosed in Muhanna in connection with the Examiner's rejection of claims for obviousness over Muhanna in view of Lambrecht et al., *infra*.

In view of the foregoing amendment of the specification to provide express written antecedent basis for the claim term "pleated", the Examiner's objection to the specification is deemed to have been fully satisfied.

The Examiner has rejected Claims 17-19, 27 and 45-47, 49 and 50 under 35 U.S.C. § 112, first paragraph, as lacking enablement for the ability of one skilled in the art to restrain the tissue during the pulling of the drawstring to fold the tissue so as to prevent the tissue from being pulled in the drawstring-pulling direction.

Applicants' specification can only be said to lack enablement for the aforementioned restraining operation (recited in step (c) of the claims) if such were to require "undue experimentation".

As held by the court in *In re Wands*, 858 F.2d 732, 8 USPQ3d 1400, 1404 (Fed. Cir. 1988), any analysis of what constitutes "undue experimentation" must take into account at least the following 8 case-dependent factors: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

When all of these *Wand* factors are considered, it is clearly evident that those skilled in the art, in this case, knowledgeable, experienced orthopedic surgeons, would very soon, if not immediately, grasp from the implantation procedure illustrated in stages in Figs. 7-10, that pulling on the drawstring without at the same time preventing the implant from being pulled in the drawstring-pulling direction will fail to achieve the

result illustrated in Fig. 10. It would take very little further reflection on this situation by an orthopedic surgeon to realize that all that is needed to prevent the tissue from being pulled in the drawstring-pulling direction during each pulling of the drawstring is for the second end of the tissue to be held stationary while pulling of the drawstring causes the first end of the tissue to fold, eventually forming the pleated implant illustrated in Fig. 10. The surgeon's hands are well-suited to simultaneously holding the implant stationary and pulling on the drawstring.

Applicants submit that when the sufficiency of the specification as an enabling disclosure is evaluated in accordance with the *Wand* factors, it can only be concluded that no undue experimentation would be required of an orthopedic surgeon in order to carry out step (c) of the method of Claim 27.

The Examiner has repeated nearly *verbatim* his previous rejection of Claims 51-53 and 56-58 as anticipated (35 U.S.C. § 102(a)) by Gabbay.

By way of further amplifying the distinctions between Gabbay's suture 50 and Applicants' drawstring and drawstring operation as presented in Applicants' previous traverse of this rejection, Applicants wish to emphasize the disparity in function between suture 50 illustrated in Gabbay Figure 4 and the drawstring component of Applicants' claimed intervertebral disc device. Gabbay states as the only function of suture 50 that it be used to permanently or temporarily sew overlapping layers 48 of tissue material constituting prosthesis 46 together. Suture 50 is not intended to be pulled so as to bunch any tissue layer or layers together in the form a pleated structure. Forming a pleated structure is not within the purview or contemplation of the Gabbay disclosure.

In order to perform its function as a drawstring and as illustrated in Figs. 7-10, drawstring 72 must be *secured* at or near first end 74 of tissue implant 71. This feature of being "secured" is required in order to prevent drawstring 72 from being

pulled or drawn away from first end 74 of implant 71 during the pulling operation. There is no comparable showing of a "secured" suture 50 in Gabbay.

Another feature of Applicants' drawstring 72 that is required for it to function as a drawstring is that there be an end portion 73 of drawstring 72 which extends beyond second end 75 of tissue implant 71 and which is adapted to being pulled. There is no comparable showing of suture 50 in Gabbay Fig. 4 as possessing an end portion extending beyond tissue layer(s) 48 much less such an end portion adapted to being pulled.

For the reasons presented in Applicants' previous traverse of this rejection and for the further reasons presented here, the intervertebral disc device of Claims 51-53 and 56-58 is considered to be novel and nonobvious over Gabbay.

The Examiner has again rejected Claims 54 and 55 for obviousness (35 U.S.C. § 103(a)) over the combined disclosure of Gabbay and Sybert et al.

Since, for reasons presented above, independent Claim 51 is considered to be patentable over Gabbay, Claims 54 and 55 depending therefrom are also considered to be patentable over both Gabbay and the combined disclosures of Gabbay and Sybert et al., the latter reference merely disclosing an implant made from natural tissue and provided as a braided construction.

The invention of dependent Claims 54 and 55 resides in the unique drawstring feature of independent Claim 51 and the singular structural relationship of the drawstring to its associated natural tissue implant enabling the implant to assume a pleated configuration when fully implanted within a disc nucleus space. There is nothing in the combined disclosures of Gabbay and Sybert et al. that so much as even hints at these features. Such being the case, Claims 54 and 55 are considered to be nonobvious, and therefore patentable, over Gabbay combined with Sybert et al.

The Examiner has again rejected Claims 17, 18, 27, 45-47, 49 and 50 for obviousness (35 U.S.C. § 103(a)) over Muhanna in view of Lambrecht et al.

The Examiner correctly characterizes ribbon 16 of Fig. 4B of Muhanna as having a "pleated" structure, i.e., an accordion-like or bellows-like configuration, and then points to twice folded sheet 14 of Fig. 3A for its disclosure of a tissue structure possessing what is referred to as "drawstring 15." For one thing, the tissue structure of Fig. 3A is not a pleated structure as is the tissue structure shown in Fig. 4B. For another, element 15 of the structure shown in Fig. 3A is described by Muhanna as a "first fastener" which indeed it is. First fastener 15 of Fig. 3A is not a drawstring and cannot function as a drawstring. It is, as Muhanna describes it, only a fastener.

Applicants' claimed method (Claim 27) calls for implanting a length of natural tissue which possesses an initial first, straightened configuration and a second, folded, or pleated, configuration. In both configurations, the tissue possesses a drawstring secured to one end, extending beyond the opposite second end and coursing through the tissue at intervals from one side to the other. If one were to lay out twice folded sheet 14 of Muhanna Fig. 3A in its original (first) straightened configuration, it would be abundantly evident that fastener 15 (untied to permit sheet 14 to assume its straightened configuration) is not secured to one end of sheet 14, does not extend beyond the opposite end of sheet 15 and does not course through sheet 14 at intervals from one side to another.

In short, there is nothing in Muhanna that even remotely resembles Applicants' drawstring and its mode of operation. Recognizing this, the Examiner relies on the disclosure of Fig. 49G of Lambrecht et al. for its illustration of an implant 400 possessing guide filament 406. The Examiner continues to maintain that guide filament 406 functions as a drawstring.

However, as Applicants' in their previous traverse of this rejection have explained at length, Lambrecht et al. control filament 406 (also referred to therein as

"guide filament 406") does not, and cannot, function in the same manner as Applicants' drawstring. The Examiner has yet to respond to the specific points of difference between Lambrecht et al. guide filament 406 and the drawstring and mode of operation of the drawstring raised by Applicants in their previous traverse. These points of difference can be restated and amplified as follows:

(1) unlike Applicants' drawstring, Lambrecht et al. control filament 406 does not pass through a multiplicity of sites;

(2) unlike Applicants' drawstring, Lambrecht et al. control filament 406 does not pass through the tissue implant from one side thereof to another along the length of the tissue;

(3) unlike applicants' drawstring, pulling on Lambrecht et al control filament 406 will not result in an implant having multiple pleated folds; and,

(4) the function and purpose of Lambrecht et al. control filament 406 are illustrated in the sequence of drawings 49A through 49G and are explained in paragraphs 0207 and 0208; there is not the slightest suggestion anywhere in this or any other drawing(s) or text of Lambrecht et al. that pulling on control filament 406 will cause implant 400 to assume a pleated configuration.

Should the Examiner continue to maintain this rejection, Applicants would appreciate each of these four specific points of difference being thoroughly addressed. As it stands, the method of Claims 17, 18, 27, 45-47, 49 and 50 is considered to be nonobvious, and therefore patentable, over the combined disclosures of Muhanna and Lambrecht et al.

The Examiner has rejected dependent Claim 19 (which specifies that in the method of independent Claim 27, the tissue be that of a small intestine submucosa) as

obvious (35 U.S.C. § 103(a)) over Muhanna in view of Lambrecht et al. as applied to Claim 27 and further in view of Sybert et al.

As Claim 27 is considered to be patentable over the combined disclosures of Muhanna and Lambrecht et al. for the reasons presented above, this claim is also considered to be patentable over these references further combined with Sybert et al., the last mentioned reference doing nothing to make up for the absence in the combined disclosures of Muhanna and Lambrecht et al. of Applicants' drawstring feature and its mode of operation.

Reconsideration and allowance by the Examiner of pending Claims 17-19, 27, 45-47 and 49-58 in light of the foregoing remarks are respectfully requested.

Respectfully submitted,



Scott Dorland
Reg. No. 51,622
Attorney for Applicant(s)

Date: 10/1/09
Scott Dorland, Ph.D.
Senior Patent Counsel
Medtronic, Inc.
2600 Sofamor Danek Drive
Memphis, TN 38132
901.399.2652 Phone

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**WEBSTER'S
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down — if you please if you wish or like; if you will; if you permit; sometimes used in ironic exclamation — please God if it pleases God; if it is God's will — please yourself to do as one wishes
pleas-ing (plē'zīn) *adj.* giving pleasure; pleasant; agreeable; gratifying — *SYN.* see PLEASANT — *pleas'ing-ly* *adv.*
pleas'ing-ness *n.*
pleas-ur-a-ble (plēz'ə-rə-b'l) *adj.* pleasant; enjoyable; agreeable — *pleas'ur-a-bil'i-ty* (-bū'ə-tē), *pleas'ur-a-bil-ness* *n.* — *pleas'ur-a-bly* *adv.*
pleas-ure (plēz'ər, plē'zər) *n.* [ME., altered < *plēsur* < MFr. *plaisir*, orig. inf.; see PLEASE] 1. a pleased feeling; enjoyment; delight; satisfaction 2. one's wish, will, or enjoyment (what is your *pleasure*?) 3. a thing that gives delight or satisfaction 4. gratification of the senses; sensual satisfaction 5. amusement; fun — *u.*, *vi.* -ured, -ur-ing (Archaic, exc. Dial.) to give pleasure to or take pleasure in — *pleas'ure-ful* *adj.*
pleas-ure is the general term for an agreeable feeling of satisfaction, ranging from a quiet sense of gratification to a positive sense of happiness; delight implies a high degree of obvious pleasure, openly and enthusiastically expressed (a child's *delight* in a new toy); joy describes a keenly felt, exuberant, often demonstrative happiness (their *joy* at his safe return); enjoyment suggests a somewhat more quiet feeling of satisfaction with that which pleases (our *enjoyment* of the recital) — *ANT.* displeasure, sorrow, vexation
pleasure principle *Psychoanalysis* the automatic adjustment of the mental activity to secure pleasure, or gratification, and avoid pain, or unpleasantness
pleat (plēt) *n.* [ME. *pletēn*, var. of *playten*; see PLAIT] a flat double fold in cloth or other material, of uniform width and pressed or stitched in place — *u.* to lay and press (cloth) in a pleat or series of pleats
pleat-er (-ər) *n.* a person or thing that pleats; specif. a sewing-machine attachment for making pleats
pleb (pleb) *n.* same as: 1. PLEBEIAN 2. PLEBS (sense 3)
plebe (plēb) *n.* [Fr. *plèbe* < L. *plebs*] 1. the plebs in ancient Rome 2. (Obs.) the common people of any nation 3. (short for PLEBEIAN) a member of the freshman class at the U.S. Military Academy or Naval Academy
plebe-i-an (plē-bē'ən) *n.* [L. *plebeius* < *plebs*, PLEBS] 1. a member of the ancient Roman lower class; opposed to PATRICIAN 2. one of the common people 3. a vulgar, coarse person — *adj.* 1. of or characteristic of the lower class in ancient Rome or of the common people in any country 2. vulgar, coarse, or common — *ple-be'i-an-ism* *n.* — *ple-be'i-an-ly* *adv.*
pleb-i-scite (plēb'ə-sīt'; chiefly Brit., -sit) *n.* [Fr. *plébiscite* < L. *plebiscitum* < *plebs*, PLEBS + *scitum*, decree, neut. pp. of *scire*, to know; see SCIENCE] an expression of the people's will by direct ballot on a political issue, as in choosing between independent nationhood or affiliation with another nation — *ple-bis-ci-tar-y* (plā-bis'ə-tēr'ē) *adj.*
plebs (plebs) *n.* pl. *ple-bee* (plē'bēz) [L., akin to *plebe*, to fill; for IE. base see PLENTY] 1. the lower class in ancient Roman society 2. the common people; the masses
plec-tog-nath (plek'tōg-nath') *n.* [ModL. *Plectognathi*, name of the order < Gr. *plektos*, twisted (< *plekein*, to braid; for IE. base see FLAX) + *gnathos*, a jaw] any of an order (Plectognathi) of bony fishes, including the triggerfishes, trunkfishes, etc., found in warm seas and having a small mouth with powerful jaws and bony or spiny scales — *adj.* of the plectognaths
plec-trum (plek'trəm) *n.* pl. -tra, -tra (-trā) [L. < Gr. *plektron*, device for plucking the lyre < *plekein*, to strike; see PLAIN] a thin piece of metal, bone, plastic, etc., used for plucking the strings of a guitar, mandolin, etc.; also *plec'tron* (-trān), pl. -tra (-trā)
pled (pled) *colloq. or dial. pl. & pp. of PLEAD*
pledge (plej) *n.* [ME. *plegge* < OFr. *piege* (or ML. *plegium*), prob. < OS. *plegan*, to guarantee, with form & meaning infl. by L. *praebere*, to offer] 1. the condition of being given or held as security for a contract, payment, etc. (a thing held in *pledge*) 2. a person or thing given or held as security for the performance of a contract, as a guarantee of faith, etc.; something pawned; hostage 3. a token or earnest 4. a drinking of someone's health to express good will or allegiance; toast 5. a promise or agreement 6. something promised, esp. money to be contributed in regular payments 7. a person undergoing a trial period before formal initiation into a fraternity — *u.* pledged, *pledging* 1. to present as security or guarantee, esp. for the repayment of a loan; pawn 2. to drink a health to; toast 3. to bind by a promise or agreement 4. to promise to give (to *pledge* allegiance, *pledge* money to a fund) 5. a) to accept tentative membership in (a fraternity) b) to accept as a pledge (n. 7) — take the pledge to take a vow not to drink alcoholic liquor
PLEDGE applies to anything given as security for the performance of an act or contract or for the payment of a debt (he gave her a ring as a *pledge*); earnest, in current usage, applies to anything given or done as an indication, promise, or assurance of more to follow (his early triumphs are an *earnest* of his success); token is used of anything serving or given as evidence of authority, sentiment, good faith, etc. (this watch is a *token* of our gratitude);

pawn now usually refers to an article left as security for the money lent on it by a pawnbroker; hostage is applied to a person handed over as a pledge for the fulfillment of certain terms or one seized and kept to force others to comply with demands
pledg-ee (plej'ē) *n.* a person to whom a pledge is delivered; distinguished from PLEDGOR
pledg-er (plej'ər) *n.* a person who pledges
pledg-et (plej'it) *n.* [C?] a small compress, sometimes medicated, used as a dressing for a wound or sore
pledg-or (plej'ər, plej'ōr) *n.* Law a person who delivers something as security; distinguished from PLEDGEE
-ple-gia (plē'jə, -jə) (ModL. < Gr. *-plēgia* < *plēgē*, a stroke, akin to *plēsein*, to strike; see PLAINT) a combining form meaning paralysis (*paraplegia*)
Plé-iade (plē'yād') [Fr.; see PL.] a group of seven French poets of the 16th cent. who favored the use of classical forms — *n.* a small group, usually seven, of brilliant persons; also *plé-iad*, *Plé-iad* (plē'yād)
Plé-i-a-des (plē'yā-dēz') *chiefly Brit., pl. (-) n. pl., sing. *Plé-iades* < L. *Pleiades* < Gr. pl. of *Pleias*, Gr. *Myth.* the seven daughters of Atlas and Pleione, placed by Zeus among the stars 2. *Astron.* a cluster of stars in the constellation Taurus, six of which are readily visible and represent the daughters of Atlas, the seventh being "lost" (the Lost Pleiad)
plein-air (plēn'ēr) *adj.* (Fr., lit., open air) designating, of, or in the manner of certain schools of French impressionist painting of the late 19th cent., engaged mainly in representing observed effects of outdoor light and atmosphere — *plein'-air'ism* *n.* — *plein'-air'ist* *n.*
plei-o- (plē'ə, -ō) same as PLEO-
Plé-i-o-cene (plē'yā-sēn') *adj.* same as PLEIOCENE
plei-o-tax-y (plē'yā-tak'sē) *n.* [PLÉIO- + -TAXY] Bot. an increase in the number of whorls in a flower
plei-ot-ro-py (plē'yō-trō-pē) *n.* [PLÉIO- + -TROPY] Genetics the condition in which a single gene exerts simultaneous effects on more than one character in the offspring; also *plei-ot-ro-pism* — *plei-ot-ro-pic* (plē'yō-trōp'ik) *adj.* — *plei-ot-ro-p'i-cal-ly* *adv.*
Pleis-to-cene (plē'stā-sēn') *adj.* [Gr. *pleistos*, most, superl. of *poly*, much (see POLY-) + -CENE] designating or of the first epoch of the Quaternary Period in the Cenozoic Era, characterized by the spreading and recession of continental ice sheets and by the appearance of modern man — the Pleistocene the Pleistocene Epoch or its rocks; see GEOLOGY, chart
ple-na-ry (plē'nā-rē, plēn'ā-rē) *adj.* [LL. *plenarius* < L. *plenus*, FULL] 1. full; complete; absolute (plenary power) 2. for attendance by all members (a plenary session) — *ple-nar-i-ly* (-rē-lē) *adv.*
plenary indulgence R.C.Ch. an indulgence remitting in full the temporal punishment incurred by a sinner
plen-i-po-ten-ti-ar-y (plēn'ī-pā-ten'shē-er'ē, -shō-rē) *adj.* [ML. *plenipotentiaris* < LL. *plenipotens*, possessing full power < L. *plenus*, full + *potens*, powerful] having or conferring full power or authority (an ambassador *plenipotentiaris*) — *n.* pl. -ar'ies a person, esp. a diplomatic agent, given full authority to act as representative of a government
plen-ish (plēn'ish) *u.* [ME. *plenissen* < MFr. *plemiser*, prp. stem of *plemir*, to fill < L. *plenus*, FULL] [Scot.] to fill up; furnish; stock
plen-i-tude (plēn'ə-tūd', -tyūd') *n.* [ME. < OFr. < L. *plenitudo* < *plenus*, FULL] 1. fullness; completeness 2. abundance; plenty
plen-i-tu-di-nous (plēn'ə-tūd'ī-nəs, -tyūd'ī-nəs) *adj.* 1. marked by plenitude; abundant; full 2. stout; obese
plen-te-ous (plēn'tē-əs) *adj.* [ME. *plēntevous* < OFr. *plēntevous* < *plente*, PLENTY] 1. marked by or being in abundance; plentiful; copious 2. producing abundantly; fruitful; productive — *plen'te-ous-ly* *adv.* — *plen'te-ous-ness* *n.*
plen-ti-ful (plēn'tī-fəl) *adj.* 1. having or yielding plenty 2. sufficient or more than enough; abundant — *plen'ti-ful-ly* *adv.* — *plen'ti-ful-ness* *n.*
SYN. — *plentiful* implies a large or full supply (a *plentiful* supply of food); *abundant* implies a very plentiful or very large supply (a forest *abundant* in wild game); *copious*, now used chiefly with reference to quantity produced, used, etc., implies a rich or flowing abundance (a *copious* harvest, discharge, etc.); *profuse* implies a giving or pouring forth abundantly or lavishly, often to excess (profuse in his thanks); *ample* applies to that which is large enough to meet all demands (his savings are *ample* to see him through this crisis) — *ANT.* scarce, scant
plen-ty (plēn'tē) *n.* pl. -ties [ME. *plēntē* < MFr. *plēntē* < L. *plēntias* < *plenus*, FULL] 1. prosperity; opulence 2. a sufficient supply; enough; in earlier use, with the article (a *plenty* of food) 3. a large number; many (plenty of errors) — *adj.* [Colloq.] plentiful; enough; ample (plenty good time) — *adv.* [Colloq.] fully; sufficiently; quite (plenty good time)
ple-num (plē'nəm) *n.* pl. -numa, -na (-nā) (ModL. < L. neut. of *plenus*, FULL] 1. space filled with matter; opposed to VACUUM 2. fullness 3. a full or general assembly, as of all members of a legislative body 4. a) an enclosed volume of gas under greater pressure than that surrounding the container b) the state of this*

fat, lpe, cūr; ten; even; is, bite; gō, hōrn, tōol, look; oīl, out; up, fūr; get; joy; yet; chin; shē; thin; shēn; sh, leisure; n, ring; e for e in ago, e in agent, i in entity, o in comply, u in focus; * as in able (ā'b'l); Fr. bāl; 6, Fr. cœur; 8, Fr. leu; Fr. mon; 8, Fr. coo; 9, Fr. due; r, Fr. cri; H, G. ich; kh, G. doch. See inside front cover. * Americanism; † foreign; * hypothetical; < derived from